Application No.: 10/613,228 -2 - Docket No.: C1037.70045US00

Reply to Office Action of October 15, 2007

AMENDMENTS TO THE CLAIMS

1. (Previously Presented) A composition comprising an immunostimulatory nucleic acid comprising the nucleotide sequence of SEQ ID NO:1.

- 2. (Previously Presented) The composition of claim 1, wherein the immunostimulatory nucleic acid consists of the nucleotide sequence of SEQ ID NO:1.
 - 3. (Original) The composition of claim 1, further comprising an antigen.
- 4. (Original) The composition of claim 3, wherein the antigen is selected from the group consisting of a microbial antigen, a cancer antigen, and an allergen.
- 5. (Original and Withdrawn) The composition of claim 4, wherein the microbial antigen is selected from the group consisting of a bacterial antigen, a viral antigen, a fungal antigen and a parasitic antigen.
 - 6-7. (Cancelled)
 - 8. (Original) The composition of claim 3, wherein the antigen is a peptide antigen.
 - 9. (Original) The composition of claim 1, further comprising an adjuvant.
- 10. (Original) The composition of claim 9, wherein the adjuvant is a mucosal adjuvant.
 - 11. (Original) The composition of claim 1, further comprising a cytokine.

Application No.: 10/613,228 -3 - Docket No.: C1037.70045US00

Reply to Office Action of October 15, 2007

12. (Previously Presented) The composition of claim 1, further comprising a therapeutic agent selected from the group consisting of an anti-microbial agent, an anti-cancer agent, and an allergy/asthma medicament.

- 13. (Original and Withdrawn) The composition of claim 12, wherein the antimicrobial agent is selected from the group consisting of an anti-bacterial agent, an anti-viral agent, an anti-fungal agent, and an anti-parasite agent.
- 14. (Original) The composition of claim 12, wherein the anti-cancer agent is selected from the group consisting of a chemotherapeutic agent, a cancer vaccine, and an immunotherapeutic agent.
- 15. (Original and Withdrawn) The composition of claim 12, wherein the allergy/asthma medicament is selected from the group consisting of PDE-4 inhibitor, bronchodilator/beta-2 agonist, K+ channel opener, VLA-4 antagonist, neurokin antagonist, TXA2 synthesis inhibitor, xanthanine, arachidonic acid antagonist, 5 lipoxygenase inhibitor, thromboxin A2 receptor antagonist, thromboxane A2 antagonist, inhibitor of 5-lipox activation protein, and protease inhibitor.
- 16. (Previously Presented) The composition of claim 1, wherein the immunostimulatory nucleic acid has a nucleotide backbone which includes at least one backbone modification.
- 17. (Previously Presented) The composition of claim 16, wherein the backbone modification is a phosphorothioate modification.
- 18. (Previously Presented) The composition of claim 16, wherein the nucleotide backbone is chimeric.

Application No.: 10/613,228 -4 - Docket No.: C1037.70045US00

Reply to Office Action of October 15, 2007

19. (Previously Presented) The composition of claim 16, wherein the nucleotide backbone is entirely modified.

- 20. (Previously Presented) The composition of claim 1, further comprising a pharmaceutically acceptable carrier.
 - 21. (Cancelled)
- 22. (Previously Presented) The composition of claim 1, wherein the immunostimulatory nucleic acid includes at least four CpG motifs.
 - 23-26. (Cancelled)
- 27. (Previously Presented) The composition of claim 1, wherein the immunostimulatory nucleic acid is formulated as a nutritional supplement.
- 28. (Previously Presented) The composition of claim 27, wherein the nutritional supplement is formulated as a capsule, a pill, or a sublingual tablet.
- 29. (Previously Presented) The composition of claim 1, wherein the immunostimulatory nucleic acid is formulated for local administration.
- 30. (Previously Presented) The composition of claim 1, wherein the immunostimulatory nucleic acid is formulated for parenteral administration.
- 31. (Previously Presented) The composition of claim 1, wherein the immunostimulatory nucleic acid is formulated in a sustained release device.
- 32. (Previously Presented) The composition of claim 1, wherein the immunostimulatory nucleic acid is formulated for delivery to a mucosal surface.

Application No.: 10/613,228 -5 - Docket No.: C1037.70045US00

Reply to Office Action of October 15, 2007

33-42. (Cancelled)

43. (Previously Presented) The composition of claim 31, wherein the sustained release device is a microparticle.

44. (Cancelled)

45. (Currently Amended) A method for stimulating an immune response in a subject in need thereof, the method comprising

administering to [[a]]the subject a therapeutic agent in an amount effective to stimulate an immune response, wherein the therapeutic agent is the immunostimulatory nucleic acid of claim 1, in an amount effective to stimulate an immune response.

- 46. (Previously Presented) The method of claim 45, wherein the subject has or is at risk of developing an infection.
- 47. (Previously Presented and Withdrawn) The method of claim 46, wherein the infection is selected from the group consisting of a bacterial infection, a viral infection, a fungal infection, and a parasite infection.
- 48. (Currently Amended and Withdrawn) The method of claim 47, wherein the viral infection is selected from the group consisting of Human immunodeficiency viruses (HIV-1 and HIV-2), Human T lymphotropic virus type I (HTLV-I), Human T lymphotropic lymphotropic virus type II (HTLV-II), Herpes simplex virus type I (HSV-1) Herpes simplex virus type 2 (HSV-2), Human papilloma virus (multiple types), Hepatitis A virus, Hepatitis B virus, Hepatitis C and D viruses, Epstein-Barr virus (EBV), Cytomegalovirus and Molluscum contagiosum virus.
- 49. (Previously Presented and Withdrawn) The method of claim 48, wherein the viral infection is a herpes simplex virus infection.

Application No.: 10/613,228 - 6 - Docket No.: C1037.70045US00

Reply to Office Action of October 15, 2007

50. (Previously Presented and Withdrawn) The method of claim 45, wherein the subject has or is at risk of developing allergy.

- 51. (Previously Presented and Withdrawn) The method of claim 45, wherein the subject has or is at risk of developing asthma.
- 52. (Previously Presented) The method of claim 45, wherein the subject has or is at risk of developing a cancer.
- 53. (Previously Presented) The method of claim 45, further comprising administering an antigen to the subject.
- 54. (Previously Presented) The method of claim 52, wherein the antigen is selected from the group consisting of a microbial antigen, a cancer antigen, a self antigen, and an allergen.
- 55. (Previously Presented and Withdrawn) The method of claim 53, wherein the microbial antigen is selected from the group consisting of a bacterial antigen, a viral antigen, a fungal antigen, and a parasitic antigen.
- 56. (Previously Presented and Withdrawn) The method of claim 54, wherein the antigen is derived from a microorganism selected from the group consisting of herpesviridae, retroviridae, orthomyroviridae, toxoplasma, haemophilus, campylobacter, clostridium, E.coli, and staphylococcus.
- 57. (Previously Presented) The method of claim 45, wherein the immune response is an antigen-specific immune response.

58-62. (Cancelled)

Application No.: 10/613,228 -7 - Docket No.: C1037.70045US00

Reply to Office Action of October 15, 2007

63. (Previously Presented) The method of claim 45, further comprising administering to the subject a second therapeutic agent.

- 64. (Previously Presented and Withdrawn) The method of claim 63, wherein the second therapeutic agent is an anti-microbial agent.
- 65. (Previously Presented and Withdrawn) The method of claim 64, wherein the antimicrobial agent is selected from the group consisting of an anti-bacterial agent, an anti-viral agent, an anti-fungal agent, and an anti-parasite agent.

66-69. (Cancelled)

- 70. (Previously Presented) The method of claim 45, wherein the immunostimulatory nucleic acid has a nucleotide backbone which includes at least one backbone modification.
- 71. (Previously Presented) The method of claim 70, wherein the backbone modification is a phosphorothioate modification.
- 72. (Previously Presented) The method of claim 70, wherein the nucleotide backbone is chimeric.
- 73. (Previously Presented) The method of claim 70, wherein the nucleotide backbone is entirely modified.

74-75. (Cancelled)

76. (Previously Presented) The method of claim 45, wherein the immunostimulatory nucleic acid is administered orally.

Application No.: 10/613,228 -8 - Docket No.: C1037.70045US00

Reply to Office Action of October 15, 2007

77. (Previously Presented) The method of claim 45, wherein the immunostimulatory nucleic acid is administered locally.

78. (Previously Presented) The method of claim 45, wherein the immunostimulatory

nucleic acid is administered parenterally.

79. (Previously Presented) The method of claim 45, wherein the immunostimulatory

nucleic acid is administered in a sustained release device.

80. (Previously Presented) The method of claim 45, wherein the immunostimulatory

nucleic acid is administered to a mucosal surface.

81-82. (Cancelled)

83. (Previously Presented) The method of claim 80, wherein the mucosal surface is

selected from the group consisting of an oral, nasal, rectal, vaginal, and ocular surface.

84. (Previously Presented) The method of claim 45, further comprising isolating an

immune cell from the subject, contacting the immune cell with an effective amount to activate

the immune cell of the immunostimulatory nucleic acid and re-administering the activated

immune cell to the subject.

85-87. (Cancelled)

88. (Previously Presented) The method of claim 45, wherein the subject is a human.

89. (Previously Presented) The method of claim 45, wherein the subject is selected

from the group consisting of a dog, cat, horse, cow, pig, sheep, goat, chicken, monkey and fish.

90-93. (Cancelled)

Application No.: 10/613,228 -9 - Docket No.: C1037.70045US00

Reply to Office Action of October 15, 2007

94. (Currently Amended) The method of claim 52, wherein the cancer is selected from the group consisting of biliary tract cancer; bone cancer; brain and CNS cancer; breast cancer; cervical cancer; choriocarcinoma; colon cancer; connective tissue cancer; endometrial cancer; esophageal cancer; eye cancer; gastric cancer; Hodgkin's lymphoma; intraepithelial neoplasms; larynx cancer; lymphomas; liver cancer; lung cancer; (e.g. small cell <u>lung cancer; and non-small cell lung cancer</u>); melanoma; neuroblastomas; oral cavity cancer; ovarian cancer; pancreas cancer; prostate cancer; rectal cancer; sarcomas; skin cancer; testicular cancer; thyroid cancer; and renal cancer.

- 95. (Previously Presented) The method of claim 45, further comprising administering an antibody specific for a cell surface antigen, and wherein the immune response results in antigen dependent cellular cytotoxicity (ADCC).
 - 96. (Cancelled)
- 97. (Previously Presented) A method for inducing an innate immune response, comprising administering to the subject the immunostimulatory nucleic acid of claim 1 in an amount effective for activating an innate immune response.
 - 98. (Cancelled)
- 99. (Previously Presented) The composition of claim 1, wherein the immunostimulatory nucleic acid molecule is up to 100 nucleotides in length.